APPLICATION

FOR

UNITED STATES PATENT

Entitled:

ARTHROSCOPIC TISSUE SCAFFOLD DELIVERY DEVICE

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ARTHROSCOPIC TISSUE SCAFFOLD DELIVERY DEVICE

FIELD OF THE INVENTION

[0001] This invention relates to surgical tools and devices for delivering a tissue implant. More particularly, this invention relates to a delivery device for arthroscopically delivering a tissue scaffold.

BACKGROUND

[0002] Injuries to soft tissue, such as cartilage, skin, muscle, bone, tendon, and ligament where the tissue has been injured or traumatized frequently require surgical intervention to repair the damage and facilitate healing. Such surgical repairs can include suturing or otherwise repairing the damaged tissue with known medical devices, augmenting the damaged tissue with other tissue, using an implant, a graft or any combination of these techniques.

[0003] One common technique for repairing diseased or injured tissue is to implant a tissue scaffold at the defect site, either alone or along with cultured and amplified cells. In the past, such scaffolds have consisted mostly of two- or three-dimensional porous scaffolds that allow cell invasion and remodeling once the scaffold has been combined with living cells and has been delivered inside the patient. Another technique is to load the tissue scaffolds with tissue fragments and then implanting the tissue-laden scaffold at the defect site. Depending where the defect is located and the size of the defect, these tissue loaded scaffolds can vary from a few millimeters to several dozen millimeters in length and width.

[0004] The current method for implanting these tissue scaffolds is by an open or mini-open surgical procedure, which increases recovery time for the patient. Although a fully arthroscopic procedure for delivering a tissue-loaded scaffold to a defect site would be advantageous because of its minimally invasive nature and reduced side effects, there is presently no convenient method for delivering the tissue-loaded scaffolds through a cannula to the defect site without the risk of damaging the scaffold in the process. Moreover, where it is necessary to deliver the scaffold to a defect in a joint, there is currently no acceptable way to arthroscopically deliver the scaffold without reducing the pressure inside the joint. It would

therefore be desirable to provide a method and device which allows delivery of a tissue loaded scaffold in a fully arthroscopic procedure. It would also be advantageous to provide a delivery device which allows the scaffold to be delivered through a small diameter tube to a defect in a joint without reducing the pressure inside the joint.

SUMMARY OF THE INVENTION

[0005] The present invention provides a small diameter delivery device capable of delivering a tissue loaded scaffold arthroscopically to a tissue defect or injury site without reducing the pressure at the injury site. The scaffold delivery device of the present invention comprises a plunger system that includes two main components: an insertion tube and an insertion rod. The first component, the insertion tube, is configured with a flared proximal end for holding a tissue scaffold prior to delivery. An elongate, hollow body extends from the flared proximal end to a distal end of the insertion tube. The elongate, hollow body defines a passageway that extends through the body for delivery of the tissue scaffold. The second component, the insertion rod, comprises an elongate body that extends into a handle at a proximal end and a tip at a distal end. The insertion rod is configured to be removably disposed within the insertion tube for sliding along the passageway to effect delivery of the tissue scaffold through the insertion tube.

[0006] The passageway of the hollow, elongate body includes a first, flared portion that gradually extends into a second, tubular portion. Prior to delivery, the tissue scaffold can be held inside the insertion tube at the first, flared portion until the insertion rod is placed on the scaffold and urged distally. The force of the tip of the insertion rod against the tissue scaffold moves the scaffold through the passageway and out the distal end of the insertion tube. The gradual taper of the passageway allows the implant to be delivered without incurring damage in the process. Due to the small diameter of the insertion tube, the tissue scaffold can be arthroscopically delivered without reducing the pressure at the implantation site.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The invention can be more fully understood from the following detailed description taken in conjunction with the accompanying exemplary drawing, in which:

[0008] FIG. 1 illustrates an exploded view of the delivery device of the present invention;

[0009] FIG. 2A illustrates a perspective view of the delivery device of FIG. 1; and

[0010] FIG. 2B is a cutaway view of the delivery device of FIG. 2A.

DETAILED DESCRIPTION OF THE INVENTION

[0011] Turning now to the drawings and particularly to FIG. 1, a delivery system 10 for delivering a tissue scaffold 12 in accordance with the present invention is shown. The delivery system 10 comprises two main components. The first component is an insertion tube 20 and the second component is an insertion rod 40. The insertion tube 20 is defined by a flared proximal end 22 and a distal end 24. Extending between these ends 22, 24 is a hollow, elongate body 26. As shown in FIG. 2B, the hollow, elongate body 26 defines a passageway 28 comprising a first, flared portion 30 that extends into a second, tubular portion 32. The first, flared portion 30 can have a curved taper in order to provide a smooth transition between the two portions 30, 32 and to avoid damage to the tissue scaffold 12 during its delivery. The first, flared portion 30 can be integral with the second, tubular portion 32. Alternatively, the first, flared portion 30 can be provided as a separate component which is then attached to the second, tubular portion 32 to collectively form the insertion tube 20.

[0012] The second component of the delivery system 10, the insertion rod 40, comprises an elongate shaft 46 that extends into a handle 48 at a proximal end and a tip 50 at a distal end. As shown, the handle 48 is configured as a contoured grip for ease of handling. It is understood, however, that the handle 48 can comprise other configurations having any shape or size appropriate for the purposes of this invention. Meanwhile, the tip 50 can be blunt, having a spherical shape as illustrated in FIG. 1 for preventing damage to the tissue scaffold 12 during the delivery. The elongate shaft 46 is configured to be removably disposed within the insertion tube 20 for sliding along the passageway 28. Sealing rings 52 can be placed on the elongate shaft 46 to help align the insertion rod 40 and prevent backflow of fluid through the insertion tube 20 during the delivery process. These sealing rings 52 can be made from a softer material than the insertion rod 40, and can be provided as separate components for adjustable placement on the insertion rod 40.

[0013] In one aspect of the present invention, the flared proximal end 22 of the insertion tube 20 has a diameter in the range of about 15 mm to about 50 mm to accommodate a variety of

sized and shaped tissue scaffolds 12 known in the art. The passageway 28 of the insertion tube 20 can have a second tubular portion 32 with a diameter in the range of about 6 mm to about 17 mm, preferably about 7 mm to about 9 mm. The spherical tip 50 can have a diameter in the range of about 6 mm to about 10 mm, preferably about 6 mm to about 8 mm. These small dimensions ensure not only that the scaffold delivery can be accomplished in a fully arthroscopic procedure, but that damage to the tissue scaffold 12 during the delivery process can be minimized. In addition, the maximum outer diameter of the elongate shaft 26, including the sealing ring 52, should approximate the diameter of the second tubular portion 32, so that backflow of fluid can be prevented and so that a closed volume within the insertion tube 20 can be attained when the insertion rod 40 is disposed within the passageway 28.

[0014] The delivery system 10 can be formed from any suitable biocompatible metal or polymer. For example, the delivery system 10 can be formed from a medical grade surgical steel, or the delivery system 10 can be formed from a sterilizable, medical grade plastic such as polycarbonate. The sealing rings 52 of the insertion rod 40 can be formed from a compliant material such as silicone. It should be understood that the present invention is not to be limited to these materials, and one skilled in the art would recognize that the delivery system 10 of the present invention can be made from a variety of other suitable materials.

[0015] The delivery system 10 of the present invention works in a plunger-like manner. In use, a patient having a damaged or diseased tissue site is prepared for arthroscopic surgery. With the insertion rod 40 separate from the insertion tube 20, a tissue scaffold 12 can be loaded into the delivery system 10 by placing the scaffold 12 within the flared portion of the passageway 28. Depending on the dimensions and shape of the scaffold 12, the scaffold 12 can be slightly folded or rolled into a configuration similar to the one illustrated in FIG. 1. The first, flared portion 30 of the passageway 28 should be configured to sufficiently allow the scaffold 12 to seat within the insertion tube 20 at the flared, proximal end 22 without too much friction.

[0016] Next, the insertion rod 40 is placed onto the tissue scaffold 12, with the tip 50 contacting the tissue scaffold 12. Applying pressure against the handle 48, the insertion rod 40 is urged down the passageway 28 of the insertion tube 20, thus sliding the tissue scaffold 12 along with the depressed rod 40 into the insertion tube 20. The tissue scaffold 12 can be slid down the

second tubular portion 32 of the passageway 28 until the tissue scaffold 12 almost reaches the distal end 24 of the insertion tube. The sealing rings 52 on the elongate shaft 46 of the insertion rod 40 help align the rod 40 inside the insertion tube 20 so that the movement of the insertion rod 40 and tissue scaffold 12 run parallel to the length of the insertion tube 20. In addition, the sealing rings also serve to prevent backflow of fluid up through the insertion tube and to maintain a closed volume between the delivery device 10 and the implant site during the delivery process.

[0017] When the surgeon is ready to deliver the tissue scaffold 12 to the damaged or injured tissue site, the insertion tube 20 along with the tissue scaffold 12 can then be inserted directly through the incision and positioned so that the distal end 24 is located where the scaffold 12 is to be delivered. The surgeon would then continue depressing the insertion rod 20 until the tissue scaffold 12 is fully exposed to the implant site. After the tissue scaffold 12 exits the distal end 24 of the insertion tube, the insertion rod 40 can be removed and the delivery system 10 can be discarded, or it can be reused if desired. Because of the small size of the delivery system 10, it is understood that the entire delivery process can be accomplished in a fully arthroscopic procedure.

[0018] The delivery system 10 of the present invention is configured to accommodate tissue scaffolds 12 of various sizes and shapes known in the art. Where the tissue scaffold 12 also requires an adhesive or glue component for securing the scaffold 12 to the tissue defect or injury, the tissue scaffold 12 along with the glue component can be loaded into the insertion tube 20, preferably with the glue component on the inside, facing towards the passageway 28. Where it is desirable to use a fixation device such as a staple or tack to secure the scaffold 12, it is contemplated that the tissue scaffold 12 can be loaded with the fixation device extending at least partially through the tissue scaffold 12. The scaffold 12 can be position within the first flared portion 30 such that the fixation device is exposed. Then, the insertion rod 40 can be depressed against the fixation device to deliver both the tissue scaffold 12 along with the fixation device to the site of implantation. In another embodiment, the insertion rod 40 can have a tip 50 which is configured (not shown) to attach to or mate with the fixation device, thereby allowing greater control over the delivery of the scaffold 12. Also, where the tissue scaffold 12 has a unique

geometry, it is contemplated that the tip 50 can be formed as a piercing tip (not shown) in order to hold the scaffold 12 in place during the delivery process.

[0019] In yet another embodiment, the insertion rod 40 and the insertion tube 20 can be connected by a trigger mechanism (not shown) similar to the depression mechanism of a caulk gun. The trigger mechanism can include a handle or grip with an attached pivoting trigger. The handle or grip can be fixedly attached to the insertion tube 20, while the trigger can be attached to the insertion rod 40. By depressing the trigger either forwards or backwards, the insertion rod 40 can be retract away from the proximal end 22 of the insertion tube 20 to enable a tissue scaffold 12 to be loaded, or advanced towards the distal end 24 of the insertion tube 20 to effect movement of the scaffold 12 through the distal end 24. It is contemplated that the configuration of the insertion tube 20 and insertion rod 40 (including the sealing rings 52) would be similar to the ones previously described. This trigger mechanism would provide the surgeon with greater control over the advancement of the scaffold 12, and better ensure the alignment of the insertion rod 40 with respect to the insertion tube 20.

[0020] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention.